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In the

Supreme Court of the United States.

OCTOBER TERM, 1944.

No. **301**

ARNER COMPANY, INC., ET AL.,
Respondents, Appellants, Petitioners,

v.

UNITED STATES OF AMERICA,
Libellant, Appellee, Respondent.

PETITION FOR WRIT OF CERTIORARI

AND

BRIEF IN SUPPORT OF SAME.

CLINTON ROBB,
HERBERT S. AVERY,
Solicitors for Appellants.



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UNITED STATES OF AMERICA,
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PETITION FOR WRIT OF CERTIORARI.

*To the Honorable the Chief Justice of the Supreme Court
of the United States and the Associate Justices Thereof.*

The petitioners, Arner Company, Inc., and Paul Case, respectfully request that a Writ of Certiorari may issue to review the judgment of the United States Circuit Court of Appeals for the First Circuit in the case of Arner Company, Inc., et al. *v.* United States of America, 142 Fed. (2d) (R., p. 20), rendered on May 4, 1944, which affirmed the judgment of the District Court entered on April 6, 1943 (R., pp. 7-9).

JURISDICTION.

The jurisdiction of this Court is invoked under the Act of Feb. 13, 1925, Chapter 229, Sec. 1 to 43, Statutes 938, U.S. Code, Title 28, Sec. 347.

This petition was filed within the three months from May 4, 1944, the date of entry of the judgment of the Circuit

Court of Appeals as required by Section 8 of the Act of Feb. 13, 1925, *supra* (U.S. Code, Title 28, Sec. 350).

Notice of the filing of this petition together with a copy of the petition, printed record and supporting brief, has been duly served by the petitioners upon counsel for the respondent and due proof of such service filed with the clerk, as required by Rule 38 of this Court.

THE QUESTIONS PRESENTED.

The questions presented are of first impression. There is a conflict of decisions between the Circuit Court of Appeals:—Fourth Circuit—*United States v. Knowlton Danderine Co.*, 175 Fed. 1022; Sixth Circuit—*Strong, Cobb Co. v. United States*, 103 Fed. (2d) 671—and the present case; which should be set at rest.

The questions are important in order to avoid unwarranted interference with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or *the bulk shipment of food or drugs for processing and repacking before distribution to consumers*. See Senate Report No. 493, Seventy-third Congress, Second Session 1934, p. 9, accompanying S-2800, one of the bills leading to the enactment of the present law.

Five fundamental questions are involved:

FIRST: Does the Food & Drug Act, so-called, of 1938, require the labeling under the provisions of Section 502 of bulk packages which are to be shipped to a processing or labeling plant and not intended for distribution to the ultimate consumer?

SECOND: Does Section 503 of the Act require bulk packages of drugs which are to be processed, repacked and labeled before being distributed to the consumer to be exempted from labeling requirements?

THIRD: Is the Administrator authorized and permitted

under the Act to promulgate regulations requiring the shipper of bulk packages of drugs which are to be processed, repacked and labeled before being distributed to the consumer, to obtain from the operator of the repacking establishment a guaranteed description of the exact form and contents of label to be attached to the retail package?

FOURTH: Does the guarantee of the operator of the repacking establishment to the shipper of the bulk package that the drugs are not adulterated or misbranded within the meaning of the Food & Drug Act constitute a sufficient compliance with the statutes involved?

FIFTH: Do the regulations established by the administrator under Section 503 (a) (1) (2), exceed the authority granted by the statute?

STATUTES INVOLVED.

This case calls for an interpretation of the provisions of the Food & Drug Act, so-called, of 1938, particularly Section 201 (k) (1) (m), (21 U.S.C.A. 321), Sections 301 (a) (21 U.S.C.A. 331), Section 502 (c) (f) (21 U.S.C.A. 352) and Section 503 (a) (21 U.S.C.A. 353) and the regulations promulgated under Section 503 (a) (1) (2).

Section 201 has the following pertinent provisions:

(k) "The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

(1) "The term 'immediate container' does not include package liner.

(m) "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such articles."

Pertinent provisions of Section 301 are as follows:

"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetics that is adulterated or misbranded."

Pertinent provisions of Section 502 are as follows:

"(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render it likely to be read and understood *by the ordinary individual under customary conditions of purchase and use* and (italics ours)

(f) unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe doses or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is *not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirements.*" (Italics ours.)

"Such drug or device shall deem to be misbranded."

The pertinent provisions of Section 503 are as follows:

(a) "The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs or devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishments."

The pertinent provisions of the regulations under Section 503 (a) are as follows:

(a) "Except as provided by paragraph (b) and (c) of this Regulation, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce, and the time of holding in such establishment, from compliance with the labeling and packaging requirements of Section 501 (c) and 502 (c) (d) (e) (f) and (g) of the Act if

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office address of such person, and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if

such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repackaging. Such person or such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the agency who requests it."

(b) "An exemption of a shipment or delivery of a drug or device under clause (1) of paragraph (a) of this Regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the drug or device comprising such shipment, delivery, or parts is adulterated or misbranded within the meaning of the Act when so removed."

STATEMENT OF THE CASE.

This is a libel for the condemnation of certain drugs alleged to have been misbranded.

The drugs were seized by the United States Marshal at the plant of Paul Case in Brockton, Massachusetts, while in the bulk package in which they had been shipped from Buffalo, New York. The package was labeled "Special Formula No. 2" and contained the following statement:

"The product contained herein must be packaged and labeled at point of destination before sale." See R., p. 13, Exhibit (A).

The drugs were to be repackaged by Paul Case for the retail trade and were not, at the time of seizure, in a package intended for the consumer.

It was alleged that the label upon the package which was seized was not such a label as was required under the Food &

Drug Act because it did not contain the required statement of the ingredients of the drugs and contained no statement warning against habit-forming qualities.

The appellants denied that the package seized was misbranded and asserted that it was exempt from the labeling requirements of the Statute as it was not the immediate container of the article intended for consumption by the public. The case was presented on an Agreed Statement of Facts, the District Court, in an opinion, held that the package was misbranded and ordered its condemnation and the appellants duly appealed from such decree of condemnation.

The libel referred to two packages containing drugs, there was actually seized one package or drum containing about 40,000 tablets of "Special Formula No. 2."

The drum when seized was on the premises of the appellant, Paul Case, in Brockton, Massachusetts. It was the original bulk package container in which had been shipped from the plant of the Arner Company in Buffalo, New York, certain pills described as manufactured according to "Special Formula No. 2."

Special Formula No. 2 was the property of the appellant, Paul Case, a trade secret. According to this formula there were manufactured by the appellant, Arner Company, certain tablets under an agreement with the appellant, Paul Case, which tablets were shipped from the plant of the appellant, Arner Company, Buffalo, New York, F.O.B., to the plant of the appellant, Paul Case, Brockton, Massachusetts, there to be repackaged by the appellant, Paul Case, for distribution to the consuming public.

The drum in which the tablets were shipped contained a label describing the contents as "Special Formula No. 2", as per Exhibit "A", attached to Agreed Statement of Facts (R., p. 13).

There is no question raised as to the adulteration of the tablets and no question raised as to the improper labeling of

the retail package or immediate container of the article intended for the consumption by the public.

As a part of the agreement for manufacture of the tablets entered into between the appellant, Case and the appellant, Arner Company, there was the following letter: (See Exhibit "C" attached to Agreed Statement of Facts, R., p. 15), which contained thereon the receipt acknowledgment of the Arner Company as follows:

"To the Arner Company, Inc., Pharmaceutical Chemists, Buffalo, New York. I, the undersigned, Paul Case, whose address is 33 Hamilton St., Brockton, in the State of Massachusetts, do hereby guarantee the Arner Company, Inc., of Buffalo, New York, that each shipment or other delivery hereinafter made of the drugs known or designed as my Formula No. 1 and Formula No. 2, is not adulterated or misbranded as of the date of such shipment or delivery, within the meaning of the Federal Drug, Food & Cosmetic Act, and is not an article which may not, under the provisions of Section 505 of the Act, be introduced into commerce. (signed) Paul Case, Owner."

Received Arner Company, Inc., April 29, 1939.

STATEMENT OF POINTS RELIED UPON IN APPEAL TO THE CIRCUIT COURT OF APPEALS.

I. The Food & Drug Act, so-called, Section 502 (c) (2), Section 502 (f) (1), Section 502 (f), do not apply to the bulk package shipment herein involved (21 U.S.C.A. 352), see Definition Labels and labeling, Section 201 (k) (m) (1) in (21 U.S.C.A. 321).

II. The bulk package herein involved is specially exempted under Section 503 (a) and Regulation (a) (1), (21 U.S.C.A. 353).

III. If not specially exempted under Section 503 (a), (21 U.S.C.A. 353), Regulation (a) (1), it is exempted under

Section 503 (a) by reason of sufficient compliance with said section by the agreement entered into between Paul Case and the Arner Company (Exhibit "C", p. 15).

IV. The regulations established by the Federal Security Administrator, so far as they may be held to apply to the bulk package herein involved, exceed the power granted under the statute and the intent of Congress in passing such statute and are wholly unwarranted and unnecessary as applying to the case at bar.

REASONS SUBMITTED FOR ALLOWANCE OF THIS PETITION.

As stated by the District Court judge in his decision, R., p. 8, the last paragraph, "The case is one of first impression."

The reasoning and decision rendered by the Circuit Court of Appeals is contrary to the reasoning and decision of the Circuit Court of Appeals of the Fourth Circuit in the case of *United States v. Knowlton Danderine Co.*, 175 Fed. 1022, contrary to the reasoning and decision of the United States Supreme Court in *McDermott v. Wisconsin*, 228 U.S. 116 and is such a marked departure from the reasoning and decision above quoted as to require a determination by this court to set at rest the conflict.

The questions presented involve an important part of certain legitimate commercial operations carried on extensively not only by the respondent, Arner Company, but by large manufacturers of drugs and chemical products throughout the country and materially affects their methods of operation.

The commercial operations involved were of such importance as to require special attention by Congress in the course of the passage of the act involved and to require special legislation therewith and requires judicial determination to set at rest the substantial doubts raised by this litigation and this libel.

Cases relied upon by the Circuit Court of Appeals to sustain their decisions are cases involving not misbranding of drugs but the adulteration. The Supreme Court has heretofore held that there was a distinct difference between the application of the statute to misbranding and to adulteration and before this distinction is obliterated an interpretation of the present act as to the points involved is required.

PRAYER FOR WRIT.

Wherefore, your petitioners, by their undersigned counsel, respectfully pray that a Writ of Certiorari be issued out of and under the seal of this Honorable Court, directed to the United States Circuit Court of Appeals for the First Circuit, commanding that court to send to this court for its review and determination, on a day certain to be therein named, a full and complete transcript of the record and also pleadings in the case entitled Arner Company, Inc., et al., Respondents, Appellants, *v.* United States of America, Libellant, Appellee, being designated and numbered on its Docket October Term, 1942, No. 3928 and that the said judgment of the Circuit Court of Appeals may be reviewed by this Honorable Court, to the end that your petitioners may have the relief therein prayed for and such other and further relief in the premises as to this Honorable Court may seem just and proper.

Respectfully submitted,

ARNER COMPANY, INC. AND PAUL CASE,
by their Attorneys,

HERBERT S. AVERY,

177 State St., Boston, Mass.

CLINTON ROBB,
Transportation Building, Washington, D. C.

CERTIFICATE.

I hereby certify that Clinton Robb of Washington, D. C., and I are counsel for the petitioners herein, Arner Company, Inc., and Paul Case; that in accordance with the request of said petitioners the within Petition has been presented; that the allegations contained in said Petition are true, to the best of my knowledge and belief; and that said Petition is, in my opinion, well founded in law and in fact and should be granted.

HERBERT S. AVERY.

COMMONWEALTH OF MASSACHUSETTS.

COUNTY OF SUFFOLK, SS.,

BOSTON, July 15, 1944.

Then personally appeared Herbert S. Avery of Boston, Massachusetts, and made oath that he caused the foregoing Petition to be prepared and signed the same and that the same is prepared with the consent of and in accordance with the request of the petitioners named therein and that the allegations contained in said Petition are true to the best of his knowledge and belief.

Before me,

A. L. KAPLAN,

[SEAL]

Notary Public.

My commission expires March 31, 1950.